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George Alexeef, Ph.D., D.A.B.T.
Deputy Director of Scientific Affairs
Office of Environmental Health Hazard Assessment
California Environmental Protection Agency
1515 Clay Street, 16th Floor
Oakland, CA 94612

Dear Dr. Alexeef:

Based on public health concerns, I am writing to request expedited listing of 1-bromopropane (1-BP) under Proposition 65. 1-BP is a new, unregulated solvent that the National Toxicology Program (NTP) Center for the Evaluation of Risks to Human Reproduction (CERHR) recently identified as an animal developmental toxicant and male and female reproductive toxicant. It is a structural analog of the human reproductive toxicant and carcinogen, dibromochloropropane (DBCP) that was developed as a substitute for ozone-depleting chlorinated hydrocarbon solvents.

As described in the attached summary, California workers may be at significant risk for reproductive damage from inhalation and dermal exposure to 1-BP used in spray adhesives, as a degreaser, and as a proposed substitute for perchloroethylene in the drycleaning industry. 1-BP poses environmental risks to the general population through air emissions from workplaces, similar to other toxic air contaminants, and possibly through the use of consumer products. The expedited listing of 1-BP under Proposition 65 would help to eliminate or reduce exposures to this unregulated reproductive toxicant.

If you have questions or need additional information, please call me at (510) 622-4900.

Sincerely,

Raymond Richard Neutra, M.D., Dr.P.H., Chief
Division of Environmental and Occupational Disease Controls

Enclosure



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1-Bromopropane

1-Bromopropane (1-BP) is a new, unregulated solvent that the National Toxicology Program (NTP) Center for the Evaluation of Risks to Human Reproduction (CERHR) recently identified as an animal developmental toxicant and male and female reproductive toxicant (1). It is a structural analog of the carcinogen and human reproductive toxicant, dibromochloropropane (DBCP). 1-BP currently is used as a solvent in spray adhesives (2), cold bath degreasing (3) and precision cleaning (4). Comexsol-one™, a product that contains >95% 1-BP, has been proposed for use in the Bay Area as a dry cleaning solvent to replace perchloroethylene. Widespread use of 1-BP as a replacement for ozone-depleting, chlorinated hydrocarbon solvents is anticipated. Information on consumer products containing 1-BP is needed. Between 1999 and 2000, 1.5 million pounds per year of 1-BP were produced and 2.8 million pounds per year imported for use in the United States (4). The Division of Environmental and Occupational Disease Control (DEODC) is concerned that use of 1-BP without appropriate hazard warnings and regulatory limits, poses significant health risks for California workers and the general population.

NTP-CERHR Conclusions

In a March 2002 report, the NTP CERHR concluded that there is sufficient evidence that inhaled 1-BP causes developmental toxicity and reproductive toxicity in male and female rats. A benchmark concentration (95% lower confidence limit) of 305 ppm was identified from a rat inhalation developmental toxicity study (5). A No Observed Adverse Effect Concentration (NOAEC) of 100 ppm for female reproduction was identified from an inhalation, two-generation reproductive toxicity study (6). A NOAEC of 100 ppm was identified for male reproduction from both the Ichihara et al. study (7) and the WIL Research Laboratories study (6). The NTP-CERHR Expert Panel considered these results relevant for human hazard assessment.

NIOSH Exposure Data

Data on exposure to 1-BP are limited. Dermal absorption of 1-BP may be a significant route of human exposure, but no data are currently available (1). Breathing zone measurements by the National Institute for Occupational Safety and Health (NIOSH) indicate that workers do inhale high concentrations of 1-BP that may put them at risk for reproductive damage. NIOSH measured 1-BP concentrations in three plants where a 1-BP-containing spray adhesive was used. The 8-hour time weighted average (TWA) exposures of 69 workers in the first plant ranged from 60-381 ppm with a mean of 169 ppm (8). Exposures of 16 workers in the second plant ranged from 18-254 ppm with a mean of 96 ppm (9). In the third plant, where local exhaust ventilation was used, the 1-BP exposures of 12 workers were 41-143 ppm with a mean of 66 ppm (10). Implementing local

exhaust ventilation and work practice controls can substantially reduce worker exposure. In the first plant, installing spray booths with local exhaust reduced the personal 8-hour TWA exposures of 30 workers to 1.2-58 ppm with a mean of 19 ppm (11). Enclosing the local exhaust ventilation in the third plant to create spray booths reduced the breathing zone samples of 12 workers to 7.7-35 ppm with a mean of 19 ppm (12). Although exhausting 1-BP out of the workplace helps to protect workers, the extent to which it may increase exposures of the general population and pose risks of adverse reproductive effects has not been determined.

Recommended and Voluntary Exposure Limits

Regulatory agencies have not yet developed exposure limits to help protect workers and the general population from the adverse health effects of 1-BP. In the absence of regulatory guidance, a range of occupational exposure limits for 1-BP have been either recommended or voluntarily adopted. Doull and Rozman (13) recommended an 8-hour TWA occupational exposure limit of 60-90 ppm with a notation for skin absorption. Albemarle Corporation is recommending an 8-hour TWA limit of 25 ppm (14) and ATOFINA (15) is recommending an 8-hour TWA value of 5 ppm. Other 1-BP manufacturers have voluntarily established 8-hour TWA occupational exposure limits that range from 25 to 100 ppm, and list the exposure limits on Material Safety Data Sheets as guidance for employers (16-20). Under a contract with the United States Environmental Protection Agency Significant New Alternatives Policy (SNAP) program, ICF Consulting recently completed a risk screen on the use of 1-BP as a substitute for ozone-depleting chemicals. Based on the results, ICF Consulting derived a Recommended Acceptable Exposure Limit (AEL) of 25 ppm for use of 1-BP in industrial settings and a reference concentration (RfC) of 1 ppm for the general population (21).

Chronic Reference Exposure Levels and Information Dissemination

Using the Office of Environmental Health Hazard Assessment's methodology for developing chronic Reference Exposure Levels (RELs), DEODC has derived a chronic inhalation REL of 0.79 ppm* for the general population. With adjustments for hours/day and days/week, this would give a workplace chronic inhalation REL of 3.3 ppm.** These values are based on the NOAEC of 100 ppm for male and female reproduction identified by the NTP-CERHR Expert Panel. Consistent with its legislative mandate to provide "early warning" regarding new and unappreciated occupational health hazards, the Hazard Evaluation System & Information Service (HESIS) Section within DEODC is developing a Hazard Alert on 1-BP for dissemination to California workplaces. Adding 1-BP to the Proposition 65 List would extend the warning about the reproductive toxicity of this multi-purpose industrial solvent to the general population, and would ensure that the warning appeared on Material Safety Data Sheets.

*NOAEC = 100 ppm, 6h/day, 7d/wk, two-generation study
NOAEC time-adjusted from 6 h/day to continuous 24h exposure = 25 ppm
interspecies uncertainty factor = 3.16 (i.e., square root of 10); intraspecies
uncertainty factor = 10
cumulative uncertainty factor = 31.6
25 ppm / 31.6 = 0.79 ppm = REL
** 0.79 ppm x 24/8 x 7/5 = 3.3 ppm = REL

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